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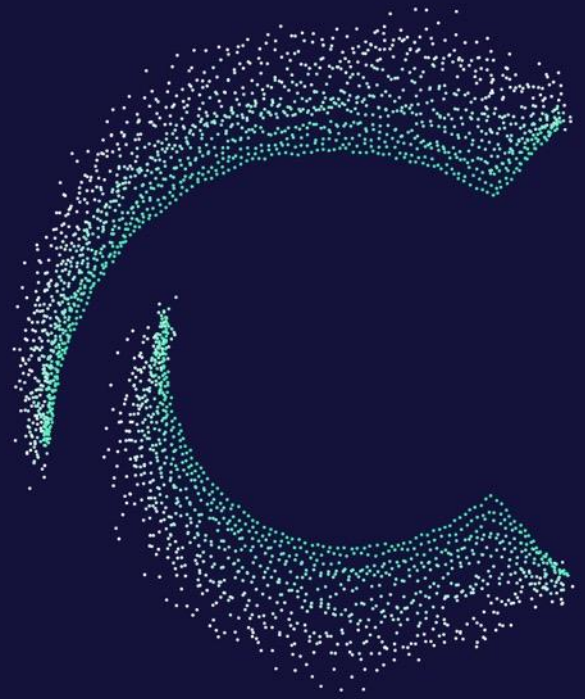
Introduction to Trialtrove



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Pharma Intelligence | CITELINE

Genmab Resource Center: https://www.citeline.com/en/resource-center/20230616/genmab

Citeline Solutions

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a norstella company

Commercial Success

Assess Risk, Predict Future Impact & Benchmark

BIOMEDTRACKER (CITELINE COMMERCIAL)
Real-time tracking of events, catalysts, and deals analysis

DATAMONITOR HEALTHCARE (CITELINE COMMERCIAL)
Market assessments, disease analysis, epidemiology and forecasts

PHARMAPREMIA (CITELINE COMMERCIAL)
Probability of success / likelihood of approval

News & Insight

SCRIP (CITELINE COMMERCIAL)
Commercial activity & market movements

IN VIVO (CITELINE COMMERCIAL)
Strategic industry analysis & market growth strategies

HBW INSIGHT (CITELINE COMMERCIAL)
OTC, dietary supplements and cosmetic markets

GENERICS BULLETIN (CITELINE COMMERCIAL)
Generics, biosimilars and value-added medicines industries

Medtech

MEDDEVICETRACKER (CITELINE COMMERCIAL)
Events, catalysts, deals and market forecasts

MEDTECH INSIGHT (CITELINE COMMERCIAL)
Commercial, Regulatory and policy perspective

Clinical Planning

Benchmark

PHARMAPROJECTS (CITELINE CLINICAL)
Preclinical to launch pipeline intelligence—drugs, companies, development statuses, targets, MOAs and more

TRIALTROVE (CITELINE CLINICAL)
Clinical trial intelligence—trial designs, endpoints & trial timing data and visualizations

SITETROVE (CITELINE CLINICAL)
Site and investigator intelligence—contact information, trial experience, and US patient proximity & counts,

SITETROVE DIVERSITY MODULE
Supplementary demographic data to support the recruitment of a diverse patient population for your trial
- Patient race
- Investigator gender

Patient Engagement & Recruitment

Optimize Enrollment & Select Sites

Find, Educate, Engage, & Enroll Participants

CITELINE CONNECT (CITELINE CLINICAL)

Find potential trial participants with:
- Recruitment marketplace with a network of 100+ partners
- Direct to patient advertising
- Real world data to locate HCPs with known patient pools
- Direct to HCP advertising

Educate potential trial participants with:
- Enterprise trial portfolio website
- Trial or disease-specific websites
- Geofenced translations

Engage potential trial participants with:
- Chatbot applications / call center
- Community portals
- Advanced trial matching
- Medical record sync
- Patient visit scheduler

Enroll potential trial participants with:
- Enrollment hub with pre-screener technology and analytics
- Referral management services

Regulatory & Compliance

Regulatory Strategy

Report & Disclose

PINK SHEET (CITELINE REGULATORY)
Regulatory and compliance journalism, analysis and insights

TRIALSCOPE INTELLIGENCE (Regulatory Intelligence Tracking)
Detailed knowledge, research and tracking of global regulatory requirements required for CTTD compliance – all in one place

TRIALSCOPE DISCLOSE (CITELINE REGULATORY)
End-to-end disclosure management and compliance SaaS Platform

Clinical trial disclosure services, from advisory to technical writing including;
- Protocol Registration
- Results Postings
- Plain Language Summaries
- Redactions

TRIALSCOPE ATLAS (CITELINE REGULATORY)
Global disclosure compliance tracking platform

Pharma Consulting and Analytics Offerings • ANALYTIC SOLUTIONS • API SOLUTIONS • CUSTOM INTELLIGENCE • RWD SOLUTIONS • PHARMA MARKETING SOLUTIONS

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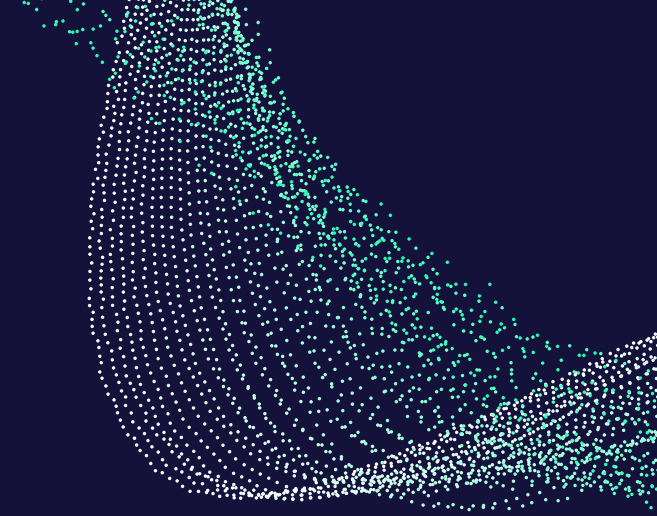
Trialtrove



Covers the Entire Public Domain

Major Sources - 58,000+ unique sources to date and growing!

- 70+ country, regional, and multinational trial registries (clinicaltrials.gov, EUCTR, Japic)
- Other trials listings sources (sponsor company registries, cooperative groups, major medical centers)
- 4,800+ companies (full coverage of pipeline, news, investor and other pages)
- All major medical meetings (250+)
- News feeds, investor presentations, SEC filings, annual reports
- Health Authority webpages
- Medical journal publication and portals
- USAN and INN lists, eMolecules, ChemSpider, and ChemIDplus
- Online resources such as Gene (formerly EntrezGene), PubMed, Espacenet

Trialtrove delivers unparalleled data to help you design and run your clinical trials with better outcomes, less risk, and lower cost

Many use cases are powered by Trialtrove

409,000+ trials (phases I-IV)

58,000+ data sources

2,000+ patient segments

1,500+ endpoints

240+ diseases across 9 therapeutic areas

200+ countries in all geographic areas

Content is manually curated and linked to Sitetrove and Pharmaprojects data

Clinical Competitive Intelligence

Anticipate competitive threats to your programs globally by understanding clinical strategies used by competitors and their likely clinical development timelines

Protocol Design and Optimization

Improve your protocol development by analyzing trends in trial designs, endpoints, and outcomes, identifying trials with positive outcomes, and finding ways to differentiate from others

Feasibility and Trial Timing Analysis

Analyze data on trial timing, enrollment metrics, study timelines, patient populations, geographic distribution, and competitive trials to inform your country selection

Over half of all trials found in Trialtrove can not be found in ClinicalTrials.gov

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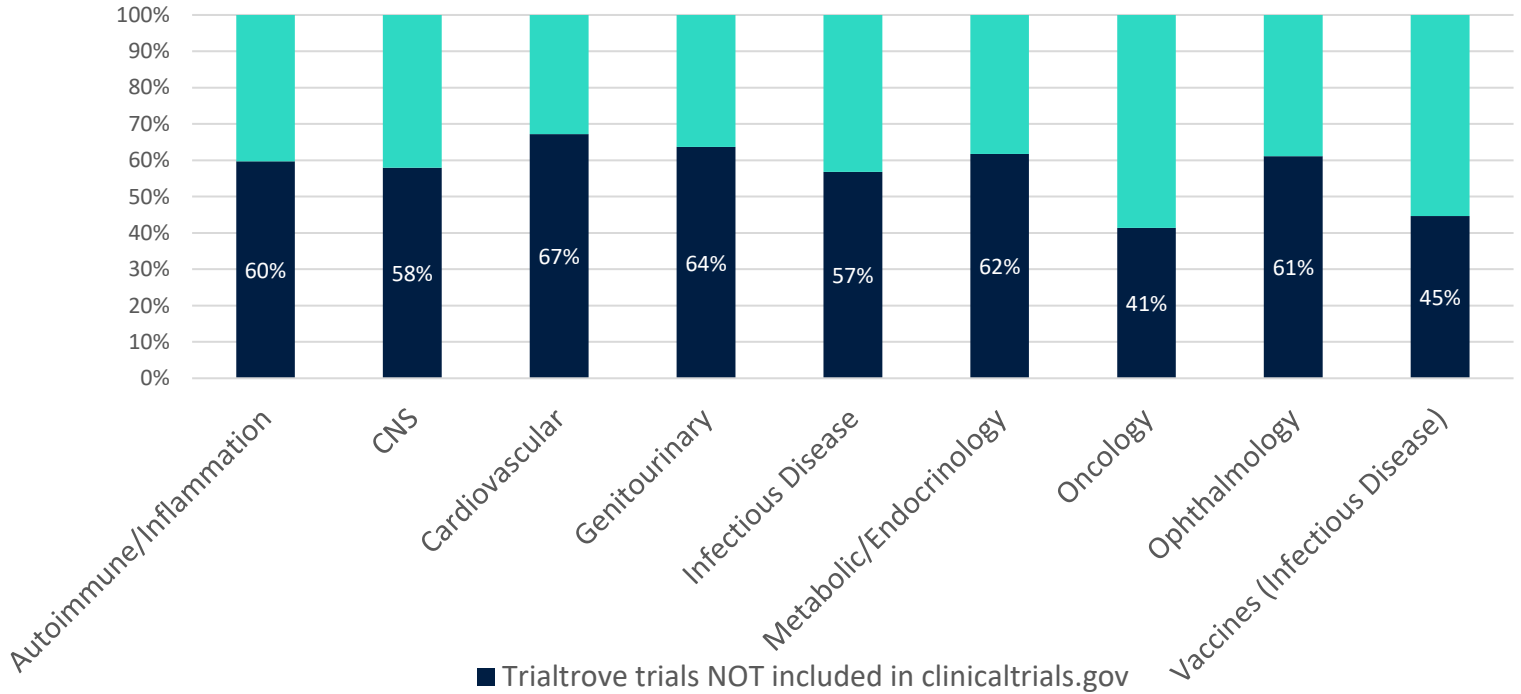
Percentage of trials in Trialtrove NOT in Clinicaltrials.gov by therapeutic area



Data as of 20 May 2024

For trials listed on ClinicalTrials.gov, Trialtrove still provides additional value

How much intelligence are you willing to do without?

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Title	Phase	Status
A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer with no Prior Systemic Therapy in this Disease Setting	III	Completed

Location	Disease	Patient Segment	Protocol IDs
Global	Breast Cancer	Estrogen receptor positive, Progesterone receptor positive, HER2 negative, First line, Stage III, Stage IV	NCT02246621, 15417, EudraCT: 2014-001502-18, I3Y-MC-JPBM IRAS ID: 164539, 15-LILA-2, JapicCTI-142749, MONARCH 3, NL51156.028.14, REec-2015-1307, Monarch-3, TrialTroveID-210961

Trial Outcome Details

Completed, Positive outcome/primary endpoint(s) met. The PFS was significantly prolonged…Verzenio dosed orally at 150 mg twice daily on a continuous schedule with an AI demonstrated a greater than 28-month median…(PFS)

Results

The PFS was significantly prolonged with a HR of 0.543 (95% CI, 0.409 to 0.723, P=.000021; median PFS: not reached in abemaciclib arm, 14.7 months in placebo arm). In MONARCH 3, Verzenio dosed orally at 150 mg twice daily on a continuous…

Treatment Plan

Participants will be randomized to abemaciclib + NSAI or placebo in a 2:1 ratio. 150 milligrams (mg) Abemaciclib orally every 12 hours plus either 1 mg anastrozole or 2.5 mg letrozole orally once daily for 28 days (28 day cycles). Placebo orally every 12 hours plus either 1 mg anastrozole or 2.5 mg letrozole orally once daily for 28 days (28 day cycles). Patients will be randomized 2:1, and stratified by nature of disease (visceral vs bone-only metastases vs other) and prior (neo)adjuvant endocrine therapy (aromatase inhibitor vs other vs none). Abemaciclib 150 mg or placebo will be given continuously PO every 12 hours until progression, along with anastrozole 1 mg or letrozole 2.5 mg once daily at the investigator's discretion, and assessments will occur every 28 days. Treatment period: until disease progression or other discontinuation criteria are fulfilled…Placebo will be supplied as capsules administered orally every 12 hours on Days 1 to 28 of a 28-day cycle. In both arms, either letrozole or anastrazole will be administered orally. Where required, anastrazole 1-mg or letrozole 2.5-mg tablets will be supplied.

Primary Endpoint Measures/Objectives

Progression Free Survival (PFS) [Time Frame: Randomization to Progressive Disease or Death Due to Any Cause (Up to 26 Months)] A 2-look group sequential design on the primary endpoint of PFS will be utilized, with 1 interim analysis and 1 final PFS analysis occurring at approximately 189 and 240 investigator-assessed PFS events. A fixed alpha-spending method will be used to maintain the cumulative 1-sided type…

This clinical trial record is further populated by our Analyst team from 110 different sources (examples below)

Example Sources Beyond ClinicalTrials.gov:

- https://www.mayo.edu/research/clinical-trials/cls-20151582
- https://clinicaltrials.ucsf.edu/trial/NCT02107703
- http://lilly.mediaroom.com/index.php?s=9042&item=137753
- http://www.quebec.canadiancancertrials.ca/trial/Default.aspx...
- http://www.clinicaltrials.jp/user/showCteDetailE.jsp?japicId=JapicCTI-14274...
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-001502-1...

+104 additional sources

Notes:
1. Data last updated in January 2019
2. Not an exhaustive record comparison

Trialtrove data is constantly curated from over 58,000 unique sources and the number of sources per TA has increased by ~40% since 2015

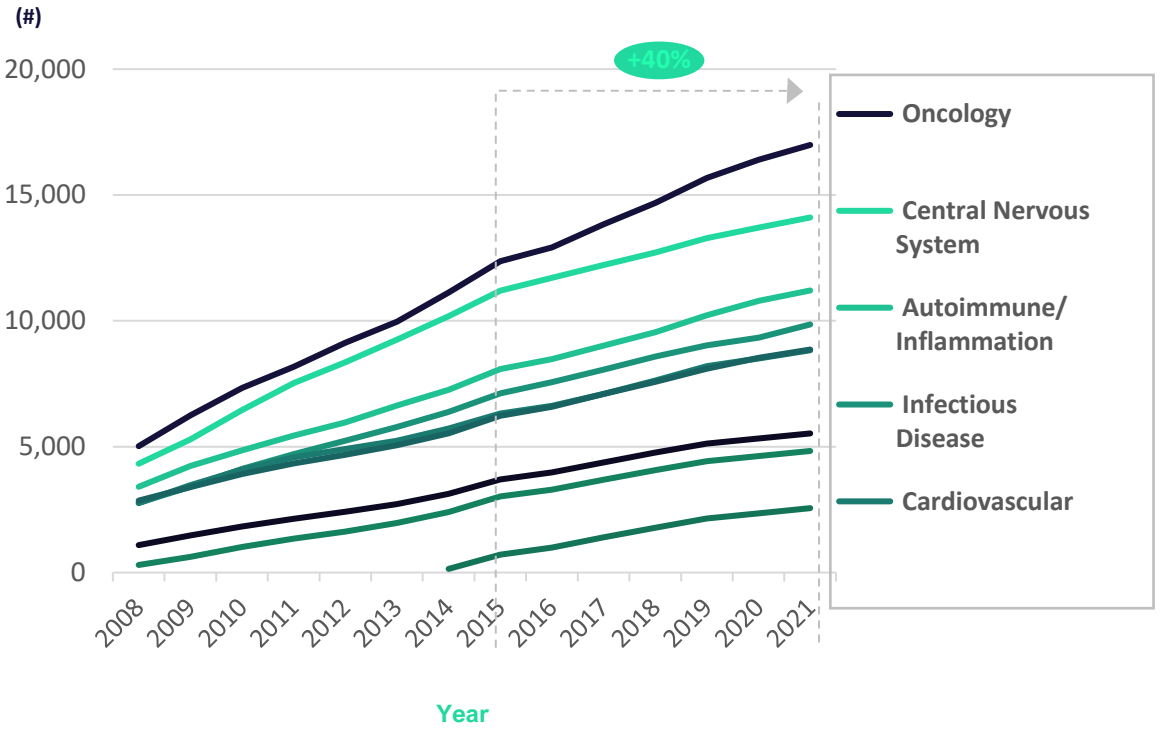
Example data sources[1]

- Country and other registries and trial listings
- Company websites, annual reports, SEC filings
- Medical meeting coverage – both large and more niche meetings
- News feeds and investor presentations
- Health authority websites
- Medical journal publications and portals
- Online sites such as PubMed

Our less obvious sources give you an edge

- Research center websites
- Community hospital websites
- University protocol/IRB approval lists
- Patient advocacy websites
- Primary research

Total sources cited in Trialtrove annually by therapeutic area[2]



Note:
1. Not an exhaustive list of data sources
2. Data collected in January of each year

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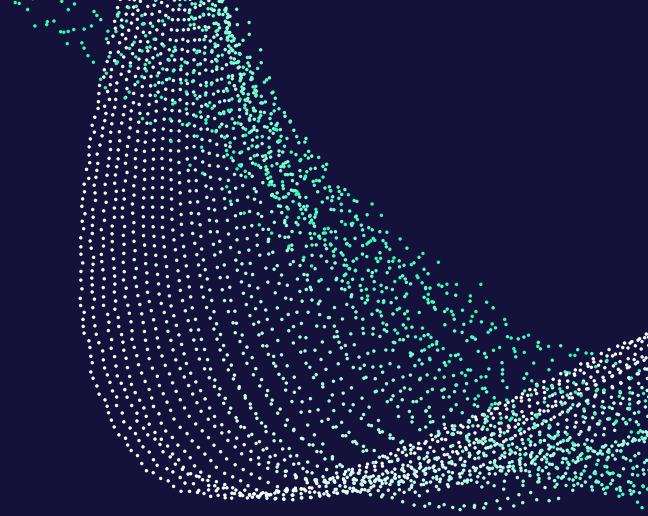
Ask the Analyst



Our team makes all the difference

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Our manually curated content is supported by 500+ therapeutic area experts/analysts in key global markets who understand your unique challenges

EXPERTISE
In-depth understanding of policy, regulation and commercial dynamics

CONNECTIONS
Extensive relationships & network of sources with regulators, associations & industry

AWARD-WINNING
Recognition of our thorough, timely, transparent & independent analyses

Our global in-house team of 50+ journalists and editors with over 1000 years' experience bring you the most important news and insights round the clock

Citeline subscribers get direct access to these experts through our “Ask the Analyst” service

Added value included in a Citeline subscription

Personalized Support

Custom research and analysis based on your question

Rapid Responses

One business day guarantee but typically much sooner

Expanded Research

For platinum clients, our team will access the full intelligence portfolio

Pharmaprojects

Could you summarize the reason for discontinuation for all PTSD assets? (e.g., xx% for Lack of Activity, xx% for not reported). Also, I would like to know the reason for discontinuation for PTSD indication, especially for GSK, Biomics, and Pfizer trials.

Trialtrove

I have an inquiry regarding the Parkinson's Study STEADY-PD III (NCT02168842). Please send me any updated information regarding patient recruitment and retention metrics and final published results.

Sitetrove

I need support in finding Investigators for a clinical trial on “Diabetes Mellitus Type 1” using vial/syringe. Target countries are Bulgaria, India, Malaysia, Philippines, Russian Federation, and United States. Is this something you could help with?

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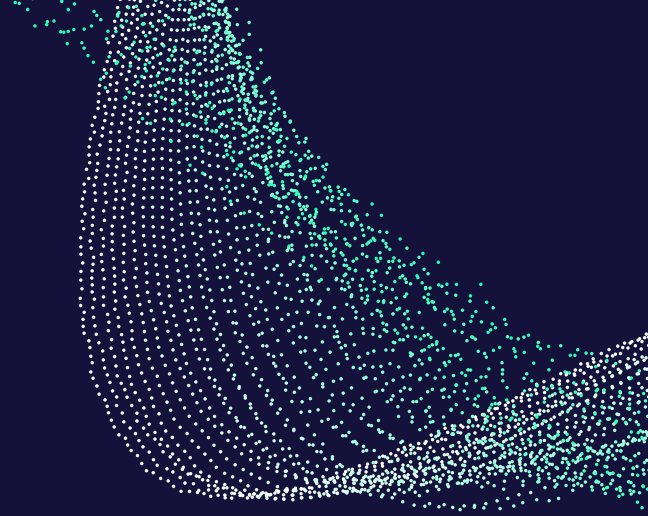
Live Demo



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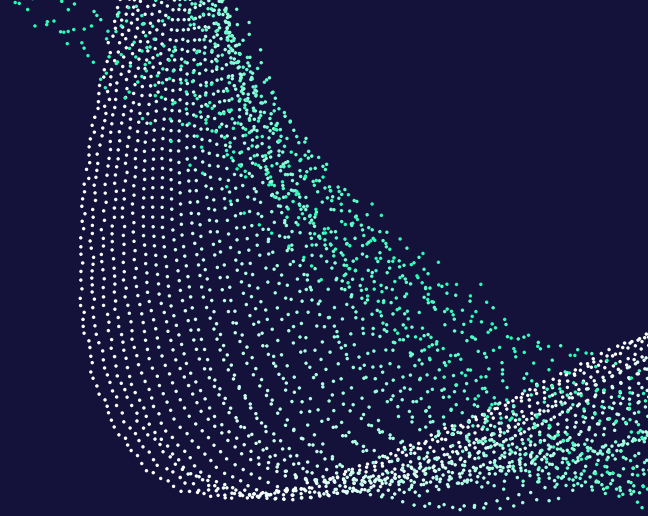
Next Steps & Resources



Next Steps & Resources

Login to your subscriptions at Citeline Product Logins. Contact clientservices@citeline.com for assistance with any login issues

Use Ask the Analyst: Ask unlimited questions with up to 3 hours of support per question, 4 hours for Platinum clients

Access Self-Guided Learning Materials in the Citeline Learning Center

Attend additional training sessions:

- Open training sessions: Citeline Training Dates
- Video Tutorials: Client Training Videos
- Bespoke group training sessions: contact training@citeline.com to a schedule a session with a member of our global training team

Book a call with your Account Manager. Your account manager is available to discuss our partnership with your organization and additional ways we can support you.

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